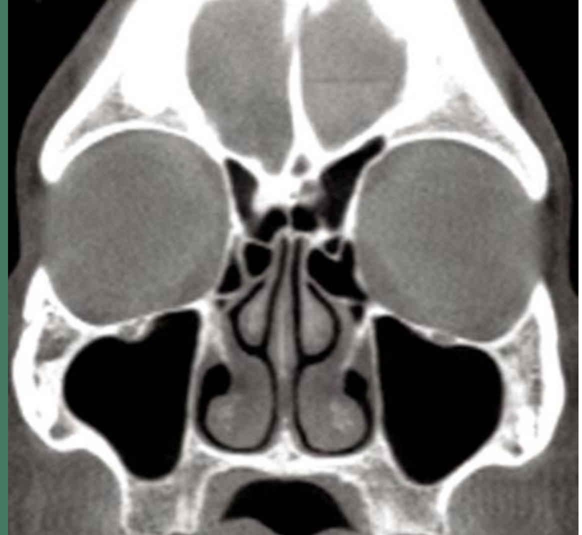

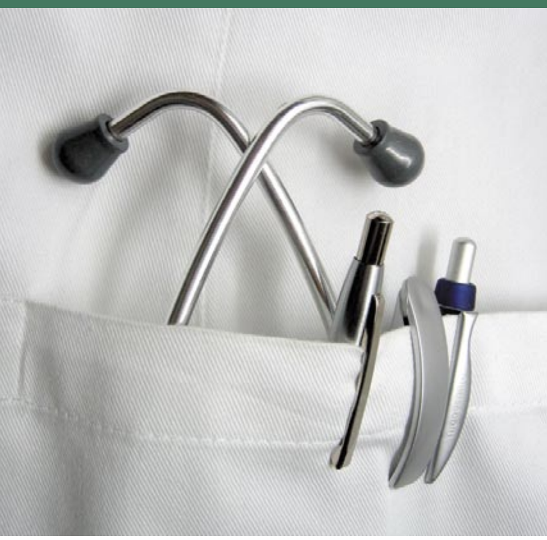

An Introduction to In-Office CT

Association of Otolaryngology Administrators

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Foreword

An Otolaryngologist seeking to improve patient care, reduce patient's costs, and increase office income, can do no better than installing a CT scanner in the office.

Over 50% of new patients that go to a typical Otolaryngologist suffer from sinusitis, nasal obstruction and congestion, or recurrent otitis media. In some practices it is over 75%.

Typically these patients have failed initial therapy by their primary physician, and now seek a more specific diagnosis and treatment. A CT scan is one of the most common tests we do to help diagnose the patient's problem.

These diseases often require an initial evaluation by the Otolaryngologist, and appointment with a radiologist, (which can range from one day to two weeks), and a return visit to the Otolaryngologist to complete the diagnosis and treatment plan.

With an in-office CT scanner, the scan is completed in less than 15 minutes. The patient is diagnosed and treated within 15-30 minutes, and charged with only one office visit and the same CT scan charge. If you were a patient, or an insurance company, which would you prefer?

CT scanners have made leaps and bounds in terms of remarkable accuracy, reduced cost of purchase, and emit up to one tenth the radiation exposure of past machines. ENT specific scanners are easy to use, and in many offices can be operated by the physician and a nurse. The space and power requirements are 1/3 that of a typical full body scanner. They usually just plug into an office wall socket. The scans are as accurate as any third generation scanner, with t1 mm. cuts, and axial, coronal, and sagital views, and can be used with any image guided surgery system.

The cost of an ENT-specific CT scanner is about one fifth the cost of a full body scanner. Offices can charge for the full technical fee and have a radiologist read the film (all the machines have teleradiology software built in), or the office can bill a global fee and provide the interpretations themselves. Head and Neck Specialty Radiologists are also available for teleconferences and consultations.

Just as in-office audiology can expedite care and enhance office revenue, a CT scanner can generate new revenue to a practice.

Many administrators are not familiar with the fact that the American Academy of Otolaryngology Head and Neck Surgery Foundation (AAO-HNSF) has published Clinical Indicators for sinus surgery. A sinus CT is *required* for surgical planning in all cases following medical therapy. A post-operative CT scan is also often indicated.

If you want to treat your patients better, faster, increase office efficiency, and generate new revenue, in-office CT scanners have now come of age for all Otolaryngologists.

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Patient Benefits of Point-of-Care CT

One of the most challenging aspects of being a part-owner of a small private practice is making decisions related to large capital purchases. When making these purchases, our practice has adopted the philosophy: "What's good for the patient is good for the practice."

Diagnosis in one visit

In many practice settings, it is obvious that many of the processes patients experience are designed for the convenience of the facility, not the patient. By incorporating services and technologies that allow the delivery of care in a more patient-centered manner, patients' time is used more efficiently allowing for faster diagnosis, treatment and relief.

Prior to having a CT scanner in our office, patients who needed scans needed to either go to the hospital or a local imaging center.

Inconveniences included:

- Making an appointment at the facility for another day, and then returning to the doctor's office for another appointment for follow-up
- Office staff spending considerable time on the phone pre-certifying examinations and scheduling these appointments
- Patients going through a lengthy registration process at the imaging center or hospital, duplicating paperwork which they already have filled out at the physician's office

Expedited patient treatment and diagnosis

In-office CT removes barriers to accurate diagnosis in patients that may have questionable but severe symptoms, and becomes more convenient for patients traveling long distances.

By scanning patients in the same office visit, particularly while they have symptoms and in conjunction with a thorough evaluation, an accurate diagnosis is achieved and proper treatment can be initiated.

Offering point-of-care CT is a great example of how practices have been able to incorporate technology that greatly benefits patients.

Patient benefits:

- Instead of three visits, which may require significant time away from work or arranging child care, patient evaluation is completed in one visit
- Both the patient and the insurance company benefit from not having the cost of an additional office visit for follow-up

- The images are always available and can be reviewed with the patient in the office. In the age of PACS (Picture Archiving and Communications System), it is amazing that we still frequently see patients who bring reports, without any opportunity to view their images. We are expected to render a diagnosis based on a report from a radiologist that we may not even know

- Our images are better because we have control of the protocols used

- With the scanner that we purchased, patient's requiring image-guidance during their sinus surgery, do not need to have a second scan. This can be decided after the imaging is completed and the patient only incurs the cost of one scan and the add-on code if image guidance is going to be used, rather than the cost and inconvenience of two scans

- The patient no longer has to go to the hospital which may provoke anxiety

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Office Benefits of Point-of-Care CT

Advantages to in-office CT imaging include:

- The control of the patient's time and convenience
- Providing correct treatment
- Easier analysis and comparison of previous studies

When patients see doctors, most are already suffering with uncomfortable symptoms. The last thing that they want to hear is that they need to go elsewhere for a CT scan in order to determine what is truly wrong.

In some cases, patients have to live with their symptoms for days or weeks until a time can be scheduled to obtain a CT scan followed by an additional appointment for diagnosis and treatment.

In office scanning gives the ability to:

- Minimize interruption to the daily lives of patients

- Increase patient compliance with having a point-of-care CT scanner

- Diagnose patients faster and begin treatment right away. This is important to patients, because they get relief from their symptoms faster. This also eliminates unnecessary trial medications for treatment of presumed diagnosis

- Control the timing and quality of our CT scans. In office CT allows for control of slice thickness, choosing pediatric or adult CT scan protocol, and choosing whether it is a full or a limited study

- Compare studies of previous scans and pull scans up right on a computer in the exam room

- Increase patient compliance. Patients are more willing to have a CT scan because it can be done in the same office visit

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Financial Feasibility

Determine who will read scans—physicians or teleradiologists

Many physicians prefer to read their in-office CT scans themselves. This means they will have to perform a CT interpretation in order for you to bill for the Professional Component (PC) of the bill. When physicians read their own scans, most practices bill globally—for both the Technical Component (TC) and PC.

Some physicians have implemented an internal review process. For example, each week a different physician does an over-read of all scans performed that week. Other practices have a weekly or monthly meeting where they review tricky scans.

Other practices prefer to send some or all scans for interpretation by a radiologist. The Professional Component is generally $40-$60 per scan (TC is generally $260-$400). Some practices bill globally and contract with a radiologist for the interpretation. This practice is under review and may soon be prohibited by changes in the Stark Law. Others bill only for the TC and have the radiologist bill for their portion—the PC.

Review records to check scan volume

Due to insurance companies' over-utilization concerns, it is important to keep your scan volume with in office CT approximately the same as the number of non-contrast sinus and temporal scans you currently order from radiology.

Some ways to find out your current scan volume include:

- Call your radiologist(s) or local imaging center where you currently have the patients' scans done
- Check internal records for the number of scans ordered weekly per physician
- If your major payers require prior authorization, look up the number of CT prior-authorizations your staff called in
- Track the number of scans ordered for 1-3 months. Be sure to track by payer. Knowing the number of scans per payer will help you get a better idea of your projected reimbursement. For example, 20% of your CT patients may come from Medicare at about $260 per scan (global bill), but 80% come from Blue Cross at $450 per scan. If you just used Medicare of just Blue Cross reimbursement amounts, your ROI figures would be skewed.

Check with insurance payers to verify reimbursement for scans

This can be as simple as calling your payer to ask how much they'll reimburse for the following CPT codes:

- 70486 sinus scan: computed tomography, maxillofacial area; without contrast material
- 70480 temporal bone scan: computed tomography, orbit, sella, or posterior fossa or outer, middle or inner ear; without contrast material
- 76376 navigation
- 76380 limited CT: computed tomography, limited or localized follow-up study

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CT Interpretation and Teleradiology

Otologic imaging

CT imaging of the temporal bones has become an important tool in the evaluation of the ear. Current technology allows for detailed depiction of the regional anatomy with submillimetric slices. In most cases, pertinent information can be obtained with a routine noncontrast study. Cases in which post-contrast imaging is helpful include patients in whom complications of otomastoiditis (e.g. sinus thrombosis, abscess formation) or mass lesions are suspected.

Any review of the temporal bones requires a survey of the following on axial and coronal imaging:

- Mastoid air cells
  - -Degree of pneumatization
  - -Presence of opacification or septal erosion

- External ear
  - -Auricle
  - -External auditory canal

- Middle ear
  - -Presence of tympanic cavity opacification
  - -Sites of potential erosion: tegmen tympani, cochlear promontory, bone overlying lateral semicircular canal
  - -Ossicular chain

- Inner Ear structures
  - -Development
  - -Presence of abnormal inner ear sclerosis or otic capsule lucency

- Facial Nerve canal
  - -Course and caliber
  - -Presence of dehiscent tympanic segment

- Major regional vascular structures
  - -High-riding jugular bulb
  - -dehiscent jugular plate
  - -aberrant internal carotid artery
  - -persistent stapedial artery

- Internal auditory canal and vestibular aqueduct
  - -Presence of abnormal enlargement

- Skull base and paranasal sinuses

Sinonasal imaging

CT imaging of the paranasal sinuses and nasal cavity plays an important role in the evaluation of rhinosinusitis and planning for endoscopic sinus surgery. In addition to imaging evidence of pathology, interpretation of CT studies of the paranasal sinuses requires knowledge of the many sinonasal anatomic variants that can have an impact on procedural planning. A review of the paranasal sinuses requires a survey of the following:

- Nasal septum
  - -deviation
  - -spurring/contact points perforation
- Anterior skull base
  Symmetry
  - -Depression/flattening
  - -Dehiscence
- Laminae papyraceae
  - -Dehiscence
- Paranasal sinuses and drainage pathways, including ostiomeatal unit (OMU)
  - -Mucosal thickening
  - -opacification/air-fluid levels
  - -density of sinus content
- Variants affecting frontal sinuses and drainage pathways
  - -Large agger nasi cell
  - -Nasofrontal beak
  - -Frontal cells
  - -Frontal bullar cells
  - -Drainage: meatal versus infundibular
- Variants affecting sphenoid sinuses and drainage pathways
  - -Onodi cells
  - -Pneumatization of anterior clinoid process
  - -bone overlying internal carotid arteries and optic nerves
  - -insertion of septations
- Variants affecting maxillary sinuses and infundibula
  - -accessory ostia
  - -Haller cells
  - -inferomedial extension of ethmoid bullae
  - -conchae bullosae
  - -paradoxical turbinates
  - -pneumatized/atelectatic uncinate processes
- Nasal cavity
  - -presence of opacification
- Nasopharynx
- Intracranial compartment and orbits

Flat-panel CT

Flat-panel CT technology provides a number of interesting possibilities, from an imaging standpoint. From an image acquisition viewpoint, flat-panel CT technology allows examinations to be readily performed in the outpatient clinic with minimal space requirement. Additionally, studies can be tailored to the degree of anatomic detail required, while keeping radiation doses to a minimum. With certain protocols, it may be possible to obtain imaging quality that surpasses that of standard multislice CT technology

The head and neck radiologist

The head and neck radiologist can be an important team member to ENT practices; typically, individuals specializing in head and neck radiology will have undergone a four-year residency followed by a fellowship in neuroradiology for one or two years. Head and neck radiologists can be helpful in answering technical questions related to protocol and examination selection, and the need for follow-up imaging or further referral. Image interpretation is the primary role of head and neck radiologists; they excel in the efficient analysis of head and neck imaging studies, allowing the clinician freedom to spend his or her time with patients and procedures, while providing reliable readings from an individual familiar with the clinical context ENT physicians deal with. They can also be helpful consultants in the setting of difficult cases, and are specifically trained to identify incidental findings of clinical importance, such as the occasional aneurysm or intracranial mass. Working with a head and neck radiologist can also aid in the implementation of state-of-the-art imaging techniques.

Teleradiology

In the past, receiving interpretations for head and neck radiology studies required affiliation with a radiologist with head and neck expertise, as well as that individual being physically available. With the advent of teleradiology, it is now possible for practices of all kinds to receive interpretations any time, from virtually any location in the world. Advantages of teleradiology include faster receipt of imaging reports, as well as the ability to have greater control over selecting those individuals responsible for radiologic interpretation. As the increase in demand for imaging services has outpaced the increase in supply of radiologists, teleradiology has been of great value to both clinicians and the imaging community to ensure that studies can be reviewed in a timely and expert fashion.

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Principles and Brief History of CT

Invention of Computed Tomography

Computed tomography (CT), sometimes referred to as computed axial tomography or computer-assisted tomography (CAT), is a type of medical imaging invented in 1967 by Sir Godfrey Hounsfield.

Hounsfield shared the Nobel Prize in Medicine in 1979 for the invention of CT with Alan Cormack, who did earlier work in image reconstruction.

Generations of Computed Tomography

First Generation CT Scanners

- Passed a very thin beam of x-rays through the object being imaged to a single detector on the opposite side
- X-ray source and detector collected data while translating across the object at a particular angle and then incremented to the next angular position to translate again
- First generation scanner designs became known as translate-rotate scanners

Second Generation CT Scanners

- Introduced in 1975
- The number of detectors were increased and arranged into a line
- The x-ray beam could be spread out into a fan beam to cover the entire line of detectors. The x-ray source and the detector were still translated and then rotated, but the number of angular positions could be reduced with the additional detectors resulting in much shorter scan times
- Scan time was still long enough to limit these scanners to head imaging

Third Generation CT Scanners

- Introduced in 1976
- Eliminated the translate portion of the acquisition by using a larger array of detectors that rotated opposite of the x-ray source in a fixed orientation
- The speed of the scanning was drastically improved and therefore the images were no longer limited to the head. Scanning of the inferior anatomy could be achieved without much interference from respiratory motion
- Third generation CT scanners make up almost all of the conventional CT scanners used clinically today

Fourth Generation

- Introduced shortly after third generation
- Use a ring of detectors that encompassed the patient and required rotation of only the x-ray source
- Eliminated artifacts caused by detector sensitivity instability. However, as detector technology improved, the fourth generation with their inefficient use of detectors was eventually dominated by the third generation.

Helical Scanning

After an initial period of rapid development, CT technology quickly became mature, and it was not until the early 1990s that further improvements were made. With the advent of slip-ring technology introduced in 1990, the x-ray tube and detector (collectively referred to as the gantry) were able to continuously rotate. Prior to that, the gantry would have to rewind after every revolution and the patient would be incremented in the axial direction.

This process would have to be repeated several times to collect contiguous slices. With the slip-ring technology, the patient is moved through the CT scanner while the gantry continuously rotates.

This type of scanning is commonly referred to as helical scanning because data is collected in a spiral pattern. The spiral data is interpolated and reconstructed into axial slices. While scan time is improved, helical scanning has a tendency to broaden slice profiles and increase the prevalence of partial volume artifacts.

Multi-Row Detector CT

Among the most recent advance in conventional CT is the addition of multiple rows of detectors. These multiple rows allow for acquisition of several axial slices in one revolution of the gantry and the data can be reconstructed with finer axial resolution.

Currently, commercially available multi-row detector CT scanners have as many as 64 slices and may soon have as many as 256. Multi-row detector CT is sometimes referred to as volume CT (VCT) since the contiguous slices are stacked together as a representative volume of the imaged object.

Volume CT

True Volume CT, using a flat-panel, two-dimensional detector, actually reconstructs the data directly into a volume from the two-dimensional x-ray projections. The flat-panel detector is a very fine array of detector elements which allows acquisition of a high resolution projection similar to a digital radiograph.
Several of these high resolution, two-dimensional projections are collected in one revolution of the gantry. From the single revolution, the imaged object can be directly reconstructed into a volume representation with exceptionally high, isotropic resolution.

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Laws

State Certificate of Need Programs

A number of states have Certificate of Need (CON) laws which require prior approval of certain capital projects for the acquisition, addition, expansion or closure of facilities, services or equipment.

CON programs were initiated in many states in the 1960s and 1970s in an effort to contain health care costs by eliminating the proliferation of unnecessary medical facilities, equipment and services. Many CON programs apply to expensive diagnostic imaging equipment, such as CT scanners, MRIs and PET scanners.

CON laws created a permit system centered on the idea that permission to acquire and operate expensive diagnostic equipment would only be granted when there was a demonstrated need within the community for this technology. Although the approval thresholds and types of diagnostic equipment and services vary from state to state, common thresholds for approval include capital expenditures above a specific dollar amount, acquisition of equipment above a specific dollar amount, and adding or expanding a clinical service.

The time required to process a CON application varies from state to state and by type of project within a state. Timeframes in uncontested CON matters typically range from 60 or 90 days to one year. In some states, competing providers have the ability to directly or indirectly challenge the grant of a CON for certain equipment, facilities or services.

Certain third party payors, such as Blue Cross and Blue Shield of Michigan, have their own equivalent standards that apply as a pre-requisite to payment for certain services. Some of these third party payor standards are called Evidence of Necessity (EON) standards and may occur in states which lack a CON program, or states in which a CON program is too weak to prevent the proliferation of what the third party payor believes to be unnecessary equipment, facilities and/or services. When considering the acquisition, expansion or replacement of diagnostic equipment, such as CT scanners, it is necessary to check with the state to see if it has a CON program and if the particular technology in question is regulated under the CON program.

Federal and State Stark Laws

Under the Federal Stark law, a physician is prohibited from making referrals for Medicare or Medicaid payable Designated Health Services (DHS) to an entity with which the physician or a member of his or her immediate family has a financial relationship, unless an exception applies.

DHS include:

- clinical lab
- physical therapy
- occupational therapy and speech pathology services
- radiology, including CT scans, MRI, x-ray and ultrasound services
- radiation therapy
- DME

- parenteral and enteral nutrients
- prosthetics and orthotics
- home health services
- outpatient prescription drugs
- inpatient and outpatient hospital services

Penalties for violating the law can be severe. They include:

- denial of payment
- refund of payment
- imposition of civil monetary penalties

Notably, the Federal Stark law is implicated when physicians provide imaging services within their offices. Once Stark is triggered, the financial relationship(s) must then fall within an applicable exception.

The most practical exception for in-office referrals is the in-office ancillary services exception. This exception is designed to protect the in-office provision of certain DHS.

In order to utilize this exception a group practice must first qualify as group practice as defined by the Federal Stark law. The in-office ancillary exception exempts services personally provided by the referring physician, a physician who is a member of the same group practice as the referring physician, an individual that is supervised by the referring physician, or if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all of the Medicare payment and coverage rules for the services.

Under the in-office ancillary services exception, DHS must be furnished to patients in the same building where the referring physicians provide their regular medical services, or in the case of a group practice, in a centralized building. These location rules were designed to give physicians and group practices an important opportunity to provide bona-fide in-office ancillary services to their patients, while at the same time preventing group practices from using the exception to operate self-referred DHS enterprises.

A group practice can satisfy the location requirement by either meeting the “same building” test or the “centralized building” test. The Stark regulations contain three alternative “same building” tests. Under all three tests, referring physicians or group practice members must have offices in the building that are normally open to their patients a requisite number of hours per week. All three tests also require that the physician regularly practices medicine and furnishes physician services for a minimum number of hours per week in that office.

Lastly, the in-office ancillary services exception requires that the services be billed by the physician performing the service (or by the physician’s group practice), by an entity wholly owned by the group practice, or by a third party billing agent.

Many state laws also contain versions of the Federal Stark law. For example, some states have legislation that mirrors the Federal Stark law but apply the law to all sources of payment, not just Medicare or Medicaid. These laws are often referred to as “mini” Stark laws. Physicians and group practices providing diagnostic imaging services through their offices must review their state’s mini Stark law to determine whether their practice is in compliance with these laws.

State Radiation Regulations

Each state has laws and agencies which regulate the proper use of radiation, radioactive material and environmental radioactive material. State involvement in radiation regulation has customarily focused on protection programs to ensure the safety of radiation producing machines such as x-ray equipment and CT scanners.

States maintain a registry of radiation emitting equipment in professional offices, diagnostic testing facilities and hospitals. These facilities and equipment are subject to periodic inspection to ensure compliance with state laws and standards.

In most states, the scope of radiation regulation has been expanded to include setting qualifications for technologists,' monitoring exposure to radiation doses, evaluating film processing and machine performance, and imposing record keeping and reporting requirements on operators.

Most recently, the scope of radiation protection programs has expanded to include collaborative efforts with equipment manufacturers and users of radiation producing equipment to reduce radiation doses, improve diagnostic methods, provide increased protection to workers, minimize errors and improve overall radiation safety. In addition, state radiation regulatory agencies work with professional societies and trade associations to develop consensus on emerging issues, such as the legality of preventative full body CT scans without an order or prescription. States coordinate and cooperate with United States federal agencies.

Two of the most important federal agencies are:

- Federal Drug Administration (FDA), which regulates the testing and use of medical equipment

- National Institute of Standards and Technology (NITS) which establishes physical radiation standards and standards for radiation measurement

    - The Physics Laboratory of NITS establishes physical standards, conducts research on radiation and collaborates with industry on applications of radiation

    - The Occupational Safety and Health Administration of NITS promotes radiation health and safety programs

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Compatibility with Imaged Guided Systems

Patient care with Image Guided Surgery

The advent of CT scanning offering three-dimensional images of the paranasal sinuses along with the knowledge gained through anatomical research resulting in the adoption of Functional Endoscopic Sinus Surgery (FESS) has brought tremendous improvement in the care of patients with paranasal sinus disease.

The persistent problems with this surgery, despite the advancements made, were that the surgeon:

- had to rely on his own experience
- encountered visual landmarks
- had crude distance measurements in order to perform FESS

In theory, surgeons had the correct tools and correct anatomy; however, patients were often incompletely treated. For example, disease that was present in the sinuses could not be eradicated due to difficulty locating the diseased areas. In addition, problems could arise from disorientation during surgery or absence of landmarks resulting in serious and even fatal complications such as orbital injury, CSF leak, carotid artery injury, etc.

Image Guidance Systems (IGS) arose in the 1990's as the next logical extension of CT scanning and FESS. This was made possible by improvements in computer technology and the ability to precisely map a point in three-dimensional space.

These two advances have allowed surgeons to integrate a CT scan with a live patient and use a series of probes or instruments to determine the exact location of a point inside a patient's nasal cavity or sinuses.

This is then demonstrated on their prior CT scan images live on a computer screen in three dimensions during surgery allowing the surgeon to have a great deal of confidence in proper anatomic location.

This allows for more complete resection of diseased tissue and also helps to prevent complications because problematic or dangerous areas can be appropriately avoided. This technology is not limited to the paranasal sinuses, but is also utilized in neurosurgery and orthopedic procedures to accomplish the same goals.

IGS's utilize CT scan data and orient the patient to the CT scan intraoperatively by using a fixed attachment to the patient's head. In some IGS's this attachment must be present during the CT scan for the CT scan to be valid during surgery. These systems then typically require a pre-operative CT scan. Other IGS's utilize numerous data collection points typically from the contour of the patient's skin of the face. These IGS's then obviously require that all of the facial skin is visible on a CT scan, but if it is, they do not require a second scan pre-operatively.

All IGS's then use the data from a CT scanner in order to function. This data is typically downloaded in DICOM format (Digital Imaging and Communications in Medicine), which is a standard radiological data format) and burned to a CD-ROM. The CD is then placed in the IGS just prior to surgery where the data is uploaded and utilized intraoperatively.

In-office CT scanners function very well for this purpose, and, in fact, have many advantages over scans performed at outside facilities (hospitals and outpatient radiology facilities):

- In-office scanners typically have the same or better resolution and image quality. (i.e., function equally well in the IGS environment)

- In-office scanning allows the office to have control over how the scans are performed to make certain they are properly done (i.e., so that the patient does not have to return for a second scan)

- The office has the actual scans circumventing numerous potential peri-operative problems

The office can download the scans to CD whenever needed. Often problems can arise with obtaining the data appropriately formatted onto a CD from outside facilities.

In summary, in-office CT scans give surgeons numerous advantages over current outpatient radiologic facility or hospital CT scanners when utilized with IGS's. Some in-office scanners may allow for future improvements in IGS technology and resolution.

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Medical Physics and Radiation Safety

Point-of-care CT allows the ENT practice to provide standard of care CT imaging in a convenient, patient-friendly environment. Because the CT scanner uses x-rays to create the image, it is essential that the ENT practice be knowledgeable about basic radiation safety concepts, regulations that govern the use of x-rays, and utilize the expertise of a medical physicist to assure safety and regulatory compliance.

Most jurisdictions require that a radiation safety officer (RSO) be identified. The RSO is the single person who is responsible to assure that the radiation is used safely, and within the requirements of state regulations. An ENT physician will usually be identified as the RSO.

A Medical Physicist is a MS or PhD physicist with education and training in the use of radiation in medicine. Medical Physics societies define a qualified medical physicist as one who is board-certified in their specialty: Diagnostic Imaging Physics, Radiation Oncology Physics, Nuclear Medicine Physics or Medical Health Physics.

Some states also require licensing or registration of medical physicists. A medical physicist will help the ENT practice to understand the applicable regulations, perform acceptance testing and periodic QC testing, prepare a Radiation safety – QC Manual, and may help to answer patient's questions in general; the medical physicist will assist the RSO with radiation safety and regulatory compliance.

Patients and staff will ask questions about the safety of radiation. The remainder of this chapter will help the ENT practice to answer those questions.

The term "radiation" means transfer of energy. X-rays are a form of electromagnetic radiation, such as light and heat. In electromagnetic radiation, energy is carried in bundles called "photons" which have no mass and travel at the "speed of light". The characteristics of electromagnetic radiation are determined by the amount of energy in each photon, and the degree of the effect is determined by the number of photons.

For example, we can see visible light because the rods and cones in the human eye are sensitive to the energy of light photons. With a small number of light photons, we can barely see (as in a dark room). In the presence of a large number of light photons, we reach for sunglasses.

The x-rays used in CT scanners have more energy in the photons than visible light, so they can penetrate the body and be used to create a CT image. We can't see x-rays because the rods and cones are not sensitive to photons in this energy range. The number of photons in the CT image is determined by the machine design and the x-ray exposure protocol chosen by the physician. CT scanners use the lowest number of photons that will produce the high-quality image needed for diagnosis. Too little radiation will produce a noisy or grainy looking image. For safety reasons, point-of-care CT scanners are limited in the amount of radiation they can produce.

The quantity of radiation is measured in units called the Roentgen, rad, rem, gray, sievert. The term milliRoentgen (mR) is used to describe $1/1000^{th}$ of a Roentgen. There are technical distinctions between these units, but they all measure exposure or dose to a person. For our purposes, 1 mR is about equal to 1 mrem or 1 mrad – units you will encounter in this chapter.

Each of us is exposed to natural background radiation every day we are on the earth. We receive about 1 mR per day from natural background radiation caused by the sun, radioactive materials in the earth's crust, including Radon. We receive this radiation to our whole bodies every day, whether or not we receive any medical radiation.

Biologic effects of radiation can be categorized as either Stochastic or Deterministic. Scientists have calculated human radiation risk based on data from animal models and people who have been exposed to radiation through medical procedures, radiation accidents, or the Japanese atomic bomb survivors. Radiation risk is conservatively calculated using the Linear no-threshold model. Many references are available on this subject.

Radiation used in head CT scanning have never been shown to produce any health effects on patients or operators who follow the basic radiation safety rules that will be described below.

The public has a general fear of radiation that has been largely formed by the way radiation has been depicted in movies and TV. Patient's fear of their overall health may also be redirected towards fear of radiation. ENT facilities should be able to answer patient's questions, explaining that the chance of any radiation injury from the CT scan is much lower than the risks we commonly encounter, such as driving in a car.

In general, we assume that lower radiation exposure means lower risk from radiation. The concept of ALARA dictates that the radiation exposure to all persons (patients, operators and others in the office, for example), be As Low As Reasonably Achievable. State radiation regulations also require this.

For example, ALARA requires that CT operators remain behind the protective lead barrier during x-ray exposure, because it is reasonable to do so.

The basic principle of radiation safety is to minimize our exposure to radiation by using the lowest exposure time, the largest distance and using radiation shielding whenever possible.

Those who use radiation in their work, such as physicians and radiologic technologists who operate CT scanners, are called "Occupationally Exposed Personnel". State regulations require that the whole body exposure to occupationally exposed persons be less than 5,000 mrem per year. (Figure 6)

Those who have a chance of receiving at least 10% of the maximum are required to wear personnel monitors (commonly called "film badges) while using x-rays. No one who follows the radiation safety rules for point-of-care CT should ever receive this 10% of the maximum permissible exposure. However, it is often a good idea to have some office personnel wear these badges, at least for the first year of operation, to document the low level of exposure.

Pregnancy and radiation

The developing embryo and fetus has been found to be more sensitive to radiation injury than the late-stage fetus, children or adults. Each patient should be asked if there is a chance that they may be pregnant before the exam. However, the radiation dose to the embryo-fetus from head CT is only slightly above background radiation, and is not a contraindication for this procedure.

Office personnel who may be pregnant have the option to declare their pregnancy in writing. Employers are required to assure that the exposure to the fetus of "Declared pregnant workers" is less than 500 mrem during the entire gestation period. No one operating the CT scanner or working within the office should ever reach this level of exposure, if proper safety procedures are followed.

In most jurisdictions, x-ray machines (including CT scanners) must be registered with the state department of health or environmental protection. Compliance with radiation regulations requires a number if important steps, and vary with jurisdiction. A medical physicist will assist with understanding and complying with the regulations.

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Utilization and Radiology Benefit Managers

Technological advancements in medical imaging have given physicians the ability to detect and diagnose disease in the earliest stages of development. This level of care has resulted in increased survival rates and fueled the demand for diagnostic imaging, particularly in an aging population. The number of Baby Boomers (between the ages of 45 and 64) is expected to reach 79 million by 2010, drastically increasing the need for imaging services.

As a result, diagnostic imaging is the fastest growing medical expenditure in the United States. The insurance industry is experiencing roughly a 15-35% annual increase in cost and utilization for imaging services.

Ultimately, the obstacles insurance companies face in today's world of imaging boil down to the need for a reduction in imaging costs, an assurance of necessity for the imaging test and concern for quality of equipment and technical competency.

Controlling Costs and Quality of Imaging

Insurance companies have responded to these obstacles by attempting to control which facilities can perform imaging ("credentialing") and whether it is appropriate to order a diagnostic scan ("appropriateness criteria" and "precertification"). In an effort to control imaging, an insurer can set up the credentialing and appropriateness criteria using a "middleman" consultant, called a Radiology Benefit Management (RBM) company, or by requiring accreditation from an independent third party credentialing organization or medical society.

The Methods and Motivation of RBM's

- Credentialing programs, precertification guidelines, assessing providers' competency to perform diagnostic imaging services and minimizing physician self-referrals are tactics considered by RBM's to control costs of imaging. The flavor of the credentialing program and precertification/utilization guidelines will depend on the particular insurance company and the particular RBM, leading to a hodge-podge of different guidelines and criteria. While the end results vary, the common theme in all these arrangements is that RBM consulting companies effectively maximize their profit by minimizing the number of scans performed. In other words, they profit by preventing scans from being performed or by denying reimbursement for scans.
- Since RBM's have a financial incentive to reduce the costs of imaging, these consultants will typically set up very restrictive credentialing guidelines, which effectively limits imaging to only a small number of select providers in an area.
- Precertification can be quite restrictive as well. Requiring physicians to obtain precertification is one of the most common containment methods employed by RBM's to reduce the annual cost and usage of imaging. Doctors who order imaging tests must telephone a call center or write via the Internet to contact reviewers armed with protocols that accept or deny requests. Because RBM's are financially motivated to reduce the cost of imaging, and not to reduce the overall cost of the healthcare being provided, they tend to set up restrictive utilization guidelines that limit the use of imaging but may surprisingly increase the use of drugs or more invasive procedures. Their incentive to deny is clearly not in the best interest of the patient. Aggressive first-tier precertification plans have the most reliable effect on bottom lines, as they deny 1 of 5 requests. With second tier, moderate management, 1 in 10 requests are denied and in the third tier, no requests are denied.

- In many cases, the administrative cost of attaining precertification can be substantial to a provider. On-site imaging, with precertification, can provide an opportunity to offset this additional administrative cost by providing an added revenue stream, especially at a time when reimbursements are declining.
- Though many insurers and their RBM's accept in-office scanning and self-referrals, there are clearly crusaders against it.

Radiology Benefit Management Players

RBM's are somewhat geographically dispersed throughout the country. The leading Radiology Benefit Management companies include:

- **American Imaging Management (AIM):** http://www.AmericanImaging.net
- **CareCore National:** http://www.CareCoreNational.com
- **MedSolutions Inc.:** http://www.MedSolutionsInc.com/home.html
- **National Imaging Associates (NIA):** http://www.NiaInc.com/index.html
- **HealthHelp:** http://www.HealthHelp.com

Different RBM's, Different Methods

- No doctor as a rule likes the concept of utilization management since it second-guesses the doctor and wedges itself between the doctor and his/her patient. Although the relationship between physician and the RBM can be difficult at times, once precertification for scanning is authorized, reimbursement is assured. Further, the Payor is assured that overutilization of in-office and off-site scanning is moderated.
- The referring doctor is required to obtain precertification whether referring the patient to an off-site scanning facility or performing the scan himself. Some RBM programs have precertification requirements for imaging which can be very time-consuming and onerous for the referring physician, while other RBM programs rely merely on an educational process to dissuade unnecessary scanning.
- An article in Managed Care Week, January 15, 2007, demonstrates these two differing philosophies. The approach of American Imaging Management (AIM) is to dissuade physicians from ordering unnecessary scans, but they won't refuse to authorize or pay for the studies. "We're not going to be in the business of denying scans, even if the best-practice pathway or best-practice recommendation isn't what the provider ultimately decides to do," says Pat Courneya, M.D., the plan's associate medical director. "We're confident an educational process will be nearly as effective as some of the more onerous prior-authorization programs…at least, effective enough for us to achieve substantial improvement." AIM requests "a few pieces of information," Courneya says, including patient demographic data, the test being ordered, clinical indications and some underlying patient medical information. "Most of the studies get approved based solely on that interaction."
- National Imaging Associates (NIA) on the other hand is a strong proponent of requiring physicians to obtain preauthorization before ordering imaging services. It is their belief that, left unmanaged, insurers' costs for high-tech imaging services will increase 20% per year, says Bob LaGalia, CFO of National Imaging Associates (NIA). NIA operates RBM programs that can reduce the trend to 2% to 3%, he says.

Alternative Measures

- In an effort to maintain quality and forego the intrinsically biased judgment of an RBM, some insurance companies have opted to "cut out the middleman" and bypass the RBM's altogether. The trend is to rely on independent, third-party organizations and medical societies to define and administer accreditation and utilization guidelines for imaging facilities.
- At present, two agencies have accreditation programs for CT imaging: the American College of Radiology (ACR) and the Intersocietal Commission for the Accreditation of Computed Tomography Laboratories (ICACTL). Other avenues for independent accreditation are expected to emerge as medical imaging continues to expand.
- Specific requirements of each program vary, but common requirements are that the imaging facility, devices and personnel are properly qualified and capable of providing safe and effective imaging. The qualifications of an imaging facility can be enhanced by appropriate partnerships with medical physicists and radiologists.
- By its very nature, an accredited facility imparts upon the qualifying doctor and facility a level of experience and professionalism resulting in the unlikelihood that ordered scans will be second-guessed by the insurer. Accreditation puts the physician and the administrator back in the driver's seat which ultimately allows them to return to quality patient care, and spend less time worrying about the random and often meaningless requirements imposed by various payors and RBM companies.
- Although accreditation will not address all aspects of the rising costs of imaging, it can weed out the alleged abusers and over-utilizers in the system. It advocates quality and experience. This will effectively reduce insurers' costs without paying a consultant RBM to do the same.
- In light of the independent nature and impartiality of these organizations, they are much more appropriate bodies to conduct credentialing, although ACR's guidelines strongly favor Radiologists as proper interpreters of scans. Fortunately, ACR's accreditation is not exclusive and a number of other medical specialties and societies have developed appropriateness criteria for their respective imaging services, such as the American College of Cardiology.

Summary

As imaging technology continues to advance, and the population continues to age, the demand for imaging services will most certainly increase. In the face of these advancements, insurers will seek out new avenues and strategies to reduce their overall costs. Over the past 5 years, and more intensely during the past few months, we have been seeing movement and acceptance toward accreditation. While the accreditation process may take several months, it will be well worth the investment to a practice. It will minimize or eliminate the hassles of reimbursement and provide a credible "stamp of approval" to imaging providers with referring physicians, third party payors, and patients. A number of Medical Physicist consulting groups offer services that help imaging providers obtain accreditation. RBM's will continue to shape their strategies to second-guess the doctor and change the course of patient care in an attempt to please the insurance industry, and ultimately their bottom line. If they push too hard, they will alienate the collective force of an angry patient population, a contrarian end for the insurer they serve. Going forward, RBM's will need to modify their tactics or be left behind in favor of the independent accreditation system, a less biased and less costly route for the insurer.

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